Supplemental COVID Face Shield – Quality Control Protocol

This quality control protocol corresponds to V3 of the **DtM COVID-19 Face Shield**. The revision of the corresponding shield can be found on the inside edge of the shield.

Appropriate Use Criteria

This supplementary face shield was created as an emergency action in effort to protect people by providing backup Personal Protective Equipment (PPE) options if the standard PPE has become unavailable. This device has not gone through the same regulatory approval process as standard PPE but has gone through a special verification process expedited strictly for the response to the COVID-19 pandemic.

The use of this supplementary face shield should always come secondary to existing PPE equipment, standards, and protocol options if available. The decision to implement this device should be made with careful consideration and under the consultation of the corresponding institution's occupational health and infection control departments.

The information included in this document provides a best effort protocol to minimize risk of viral transmission during assembly and delivery, as well as produce face shields whose quality is as consistent as possible.

Manufacturing Protocol

This supplementary face shield consists of three (3) components: the Shield, the Cradle, and an adjustable Elastic Strap. The shield and elastic strap can be purchased off-the-shelf, however, the cradle must be locally manufactured. This protocol assumes the Cradle will be manufactured via 3D printing.

3D Print Collection Steps

Each 3D printer, all of the parts that it produces, and each spool of filament used for that printer should only be handled by one person. This is to reduce the risk of transmission via shared surface contact.

1. Prior to printing, obtain a clean bag or box to place finished prints inside. The container must be able to be closed.
2. Take a new, clean piece of paper and write your initials on it, leaving room for several other handlers' initials. This will be known as the **Handler Tracking Sheet.**
3. Securely tape the Handler Tracking Sheet to the outside of the container.
4. Once a newly printed Cradle has cooled, it should immediately be placed in the container. Do not place any Cradles from another handler's machine in that same container.
5. When the container is full, close it and prepare a new container.

3D Printer Settings

The following settings are recommended when 3D printing the Cradle. This ensures that each print is of a consistent build regardless of printer and allows printing to be distributed across multiple 3D printing partners. All settings not listed should be adjusted according to the specific 3D printer to ensure a structurally sound part. The following settings assume a 0.4mm nozzle.

- Layer height: 0.2mm
- Number of perimeters: 3
- Fill density: 30%
- Fill pattern: Grid
- Top/bottom fill pattern: Rectilinear
- Number of solid top Layers: 5
- Number of solid bottom layers: 4
- No skirt or brim
- No supports

3D Printing Steps

Exact printing steps will vary by specific 3D printer used. Follow original manufacturer's instructions.

Assembly Protocol

Preparatory Steps

1. Disinfect the work environment.
2. Perform hand hygiene procedures.
3. Don a clean pair of gloves.
4. Prepare a clean bag or box to contain the fully assembled parts.
5. Take one container of manufactured cradles and remove the Handler Tracking sheet.
6. Add your initials to the **Handler Tracking Sheet** and tape the sheet to the outside of the new bag or box.

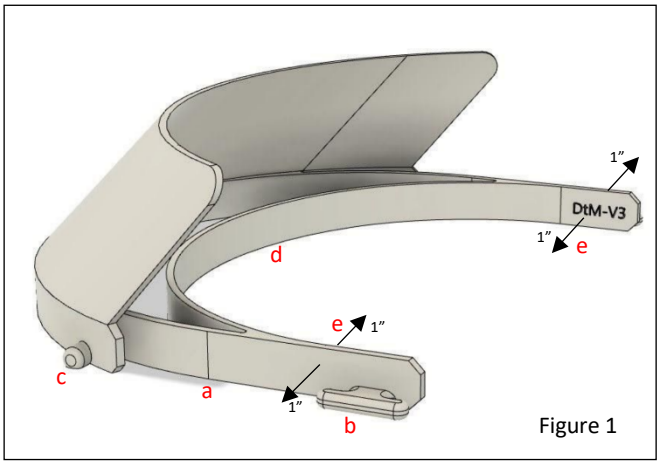

Figure 1

Assembly Steps

1. Take a single Cradle and Identify the flat face, this will indicate the bottom of the Cradle (label “a” in **Fig. 1**).
2. Perform a bend test on the Cradle by pressing inward on the outside of two edges with gentle to medium pressure, then pressing outward on the inside edges. Ensure the Cradle does not crack, snap, or otherwise show signs of distress under 1 inch of deflection (label “e” in **Fig. 1**).
3. (Optional) Place a strip of micro-foam surgical tape on the inside edge of the Cradle (label “d” in **Fig. 1**) to increase comfort while wearing the face shield.
4. Take one elastic strap and slide it through the two attachment posts on either side of the Cradle positioning it two holes in from the edge of the elastic strap (label “b” in **Fig. 1**).
5. Holding the Cradle in your non-dominant hand, secure one of the outer holes in the Shield to the Cradle peg (label “c” in **Fig. 1**). Pull the Shield across the Cradle so that the middle and remaining edge holes line up with the pegs on the Cradle. The shield should gently snap into place.
6. (Optional) Place a piece of tape over the 3 mounting holes/pegs in the face shield to fully seal any remaining gaps.
7. Turn the face shield so the front is facing the ground and hold it by the forehead visor. Gently shake the face shield to ensure that the shield is securely fastened and will not fall off during use.
8. Do a final inspection of the mask with all components assembled to ensure nothing is damaged and everything has been assembled properly.
9. Disinfect via the Disinfecting Steps below.

10. Repeat for the next Cradle in the same container as this one. If the container is empty, follow the Interstitial Steps outlined below.

NOTE: *If assembly permits deliver pre-made Shields separately in a sealed container such as a bag with a knot and zip-tie or equivalent.*

Interstitial Steps

Each time assembly has been completed for a single container of manufactured parts, complete the following steps.

1. Seal the filled container of newly assembled face shields. Options include either double bagging assembled face shields with a knock on both bags and a zip-tie on the outer bag or putting a single bag knot and a zip-tie into a box. Or an equivalent procedure.
2. Doff and carefully dispose of gloves.
3. Perform hand hygiene procedures.
4. Don a new pair of gloves.
5. Prepare a clean bag or box to contain the fully assembled parts.
6. Take one container of manufactured cradles and remove the Handler Tracking Sheet from the outside.
7. Add your initials to the Handler Tracking Sheet and tape the sheet to the outside of the new bag or box.
8. Perform Assembly Steps above.

Disinfecting Steps

Using one of the recommended disinfecting products from the list outlined in **Appendix A**, prepare to perform the following steps.

1. Wipe down and disinfect the all faces and features on the Cradle.
2. Wipe down and disinfect both sides of the clear plastic Shield.
3. Ensure the surface of the Shield is visibly wet with the disinfectant product for the duration of the contact time as defined by the EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2 (https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2).
4. Wipe any excess disinfectant and dry the face shield using a clean paper towel

Delivery Protocol

When delivering a container of Cradles from a manufacturing unit to an assembly unit or when delivering a container of assembled face shields from the assembly unit to the final drop-off point, follow the steps outlined below.

Pick-up Steps

1. Once at the pick-up location, perform hand hygiene procedures.
2. Don a new pair of clean gloves.
3. Ensure that the container of parts is closed.
4. Add your initials to the Handler Tracking Sheet.
5. Load containers into the delivery vehicle, ideally using a trunk door.
6. Doff and dispose of gloves after all containers of parts from one location have been loaded into the vehicle, and before entering the vehicle.

Drop-off Steps

1. Once at the drop-off location, perform hand hygiene procedures.
2. Don a new pair of clean gloves.
3. Remove the containers and leave at the designated drop-off site.
4. Once all containers have been dropped-off, doff and dispose of gloves.
5. Perform hand hygiene procedures.

Appendix A: Recommended Disinfectants

From the EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2 (https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2), it is recommended to use the following four solutions for the disinfecting procedures of the face shield. Note: the following list is in preferential order and have been tested with this device.

1. Super Sani-Cloth
2. 10% chlorine bleach solution (*May fog Shield over time)
3. CaviWipes
4. Soap and water

Appendix B: Functional Testing of DtM COVID-19 Face Shield

The following test protocol has been followed to ensure the safety of healthcare professional.

Donning & Doffing: Don and doff the face shield 10 times – **Pass** (The device should hold up well past this amount)

Slash Resistance: 20CC bolus of water delivered over 1 second at the center of the shield repeated 5 times – **Pass**

Face Shield Securement & Range of Motion: With the face shield on, look left, right, up, down, and shake head yes and no - **Pass**

Figure 2: Splash Resistance Test

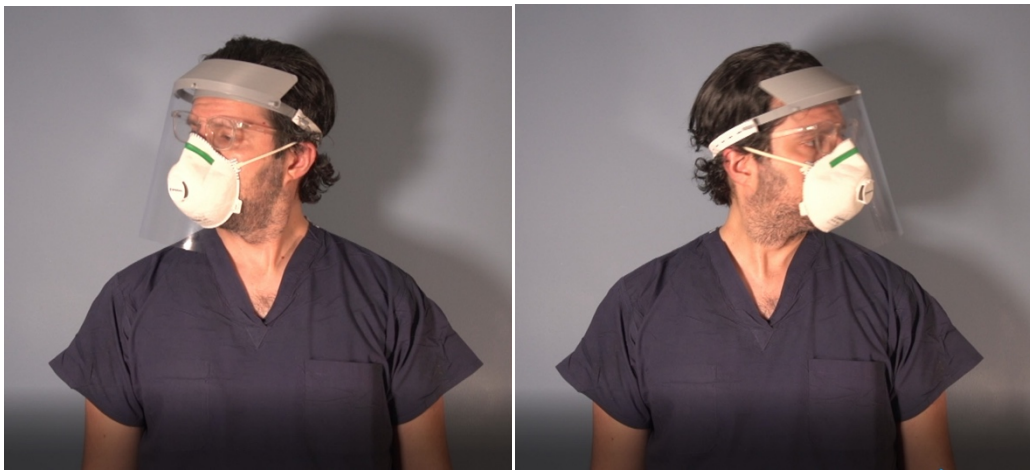

Figure 3: Range of Motion Test

Appendix C: Material Selection of DtM COVID-19 Face Shield

Cradle

Material- PLA (Polylactic Acid) has been chosen as the 3D-printing filament of choice as it is most readily available and can be printed on nearly every FDM 3D printer.

Intended Use- The cradle sits on the care provider's forehead, provides a rigid structure to attach the shield, and prevents any potential fluid from landing on the patent care provider's face from above.

Cleaning Method- Test prints of PLA cradles were used for the following tests. Four cleaning products approved by the CDC were used to wipe down the surface of the part. These include: a soap and water solution, Super Sani-Wipes, a 10% bleach solution, and CaviWipes. Surfaces were wiped dry when testing with a water-based solution and left to air dry when using an alcohol-based solution. 10 cleaning and drying cycles were performed.

Observed Results- There were no observable changes to the surface finish, color, or strength of the PLA cradle and no degradation of the materials was observed.

Shield

Materials- Four off-the-shelf transparent plastics used for overhead transparencies and binder separation were tested. These include: Highland Transparency sheets, Corporate Express transparencies, Avery binder dividers, and GBC Clearview presentation covers.

Intended Use- The secured shield will aid in protecting healthcare professionals from potential fluid splashes. The shield portion of the PPE is considered semi-reusable. It should be disposed of if damaged.

Cleaning Method- Four cleaning products were tested on each of the four varieties of sheet plastic. Soap and water, Super Sani-Cloth wipes, water with a 10% bleach solution, and CaviWipes were tested. Both the front and back surfaces were tested to eliminate potential error introduced by unexpected manufacturing surface treatments of the plastic.

Observed Results- CaviWipes and soap and water were observed to have left a small amount of residue on the surface that would eventually cloud the transparent plastic and limit visibility for the user. The Super Sani-Cloth and the water with 10% bleach left little to no residue or cloudiness in the plastic.

Recommendations- While all four cleaning products successfully disinfect the face shield, due to the least observed changes in transparency and the ubiquity of Super Sani-Cloth in clinical spaces it is recommended to use this product if available.

Images:

Plastic sheets before disinfection:

Figure 4: Corporate Express

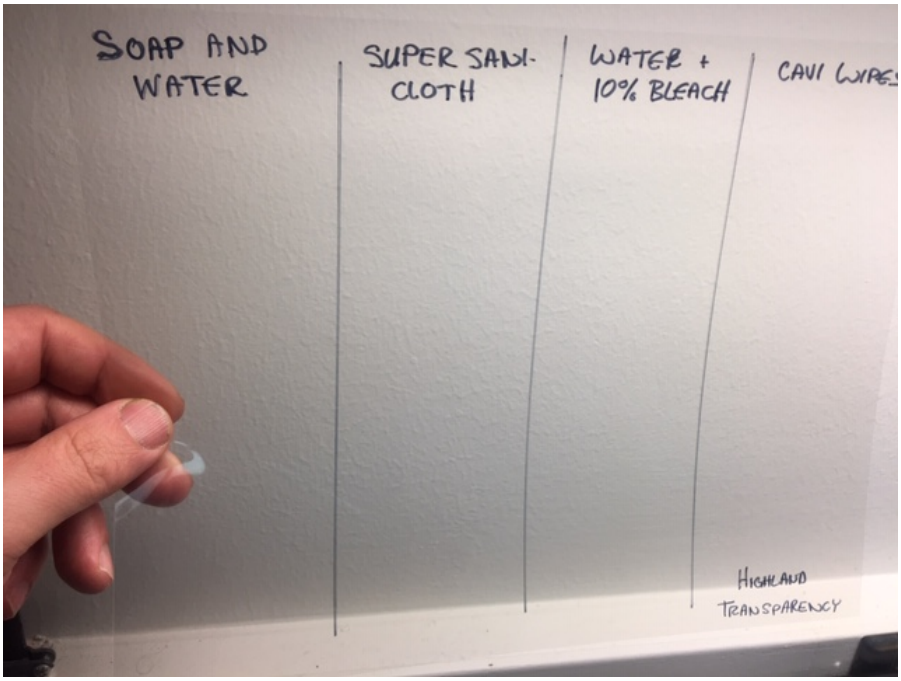

Figure 5: Highland Transparency

Figure 6: GBC ClearView

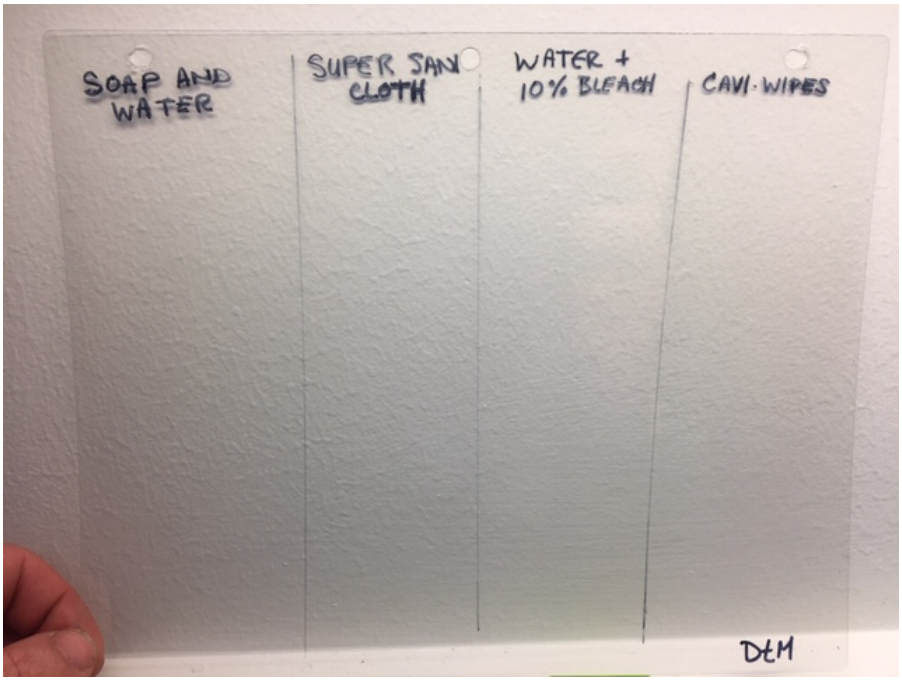

Figure 7: Avery 16741

Plastic sheets after cleaning:

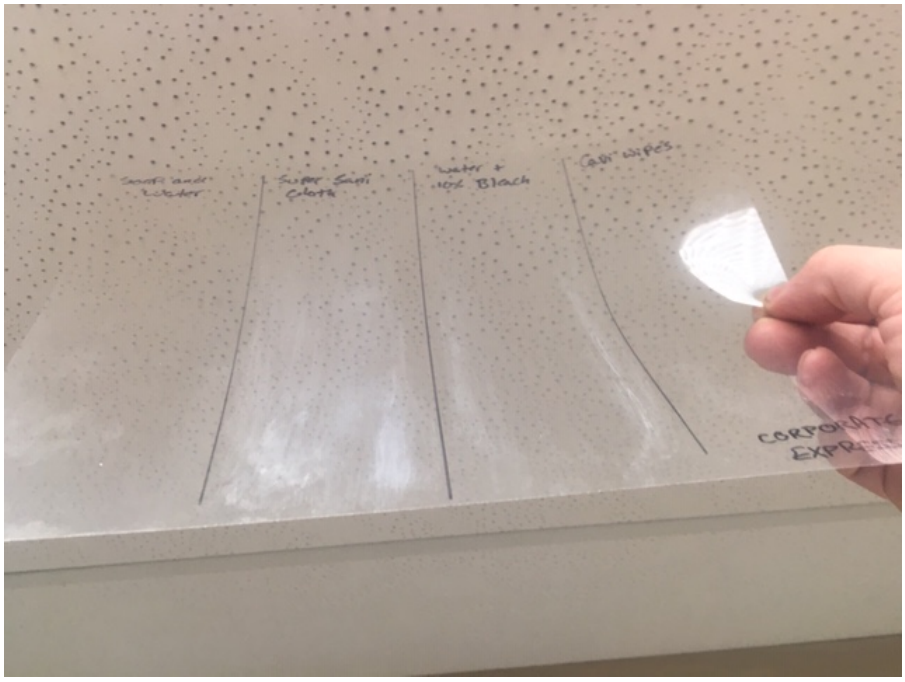

Figure 8: Corporate Express

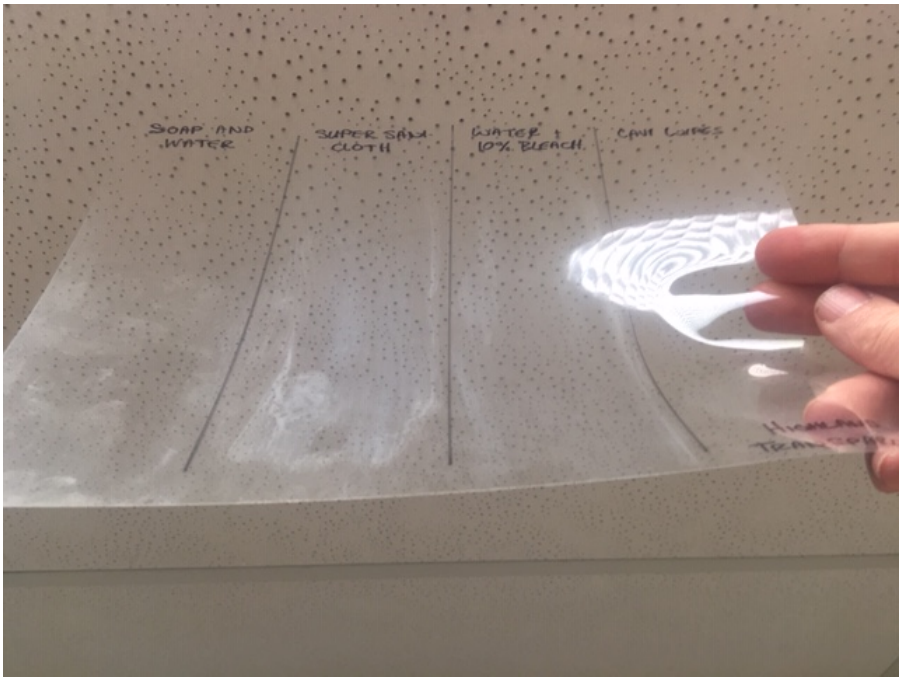

Figure 9: Highland Transparency

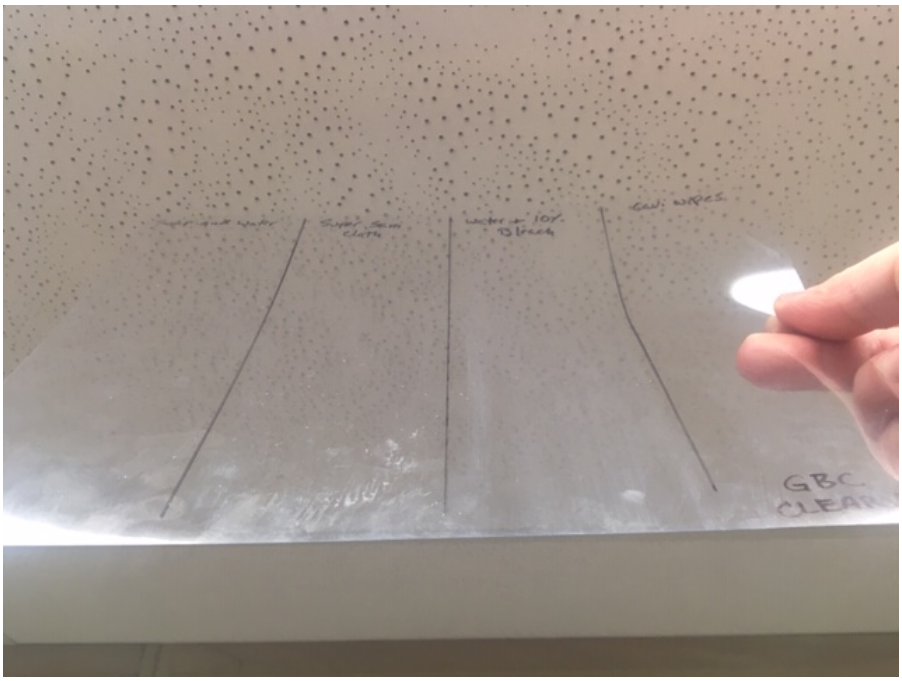

Figure 10: GBC ClearView

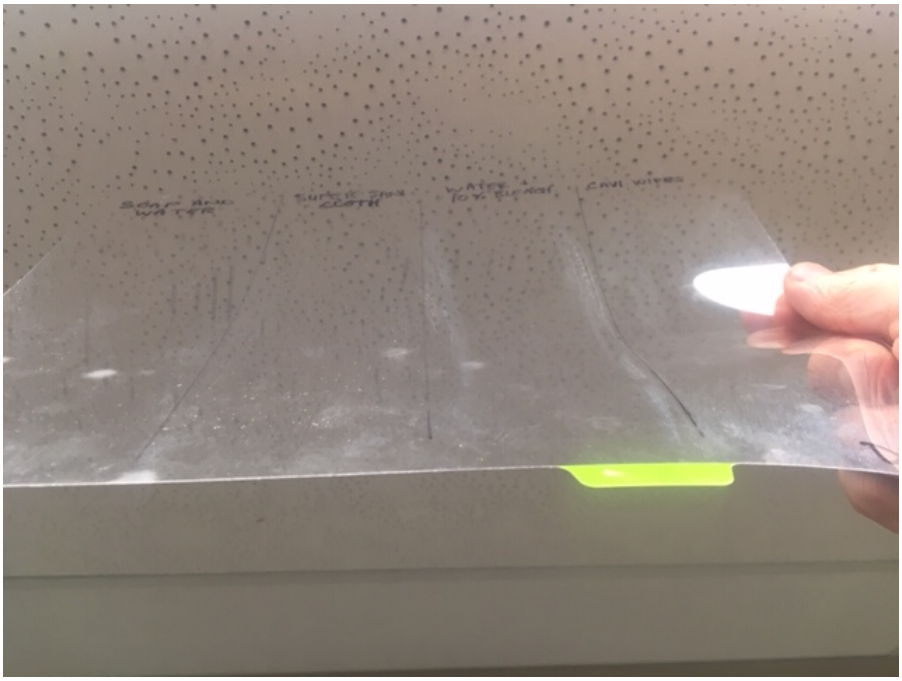
Figure 11: Avery 16741

PLA 3D-printed parts before disinfection:

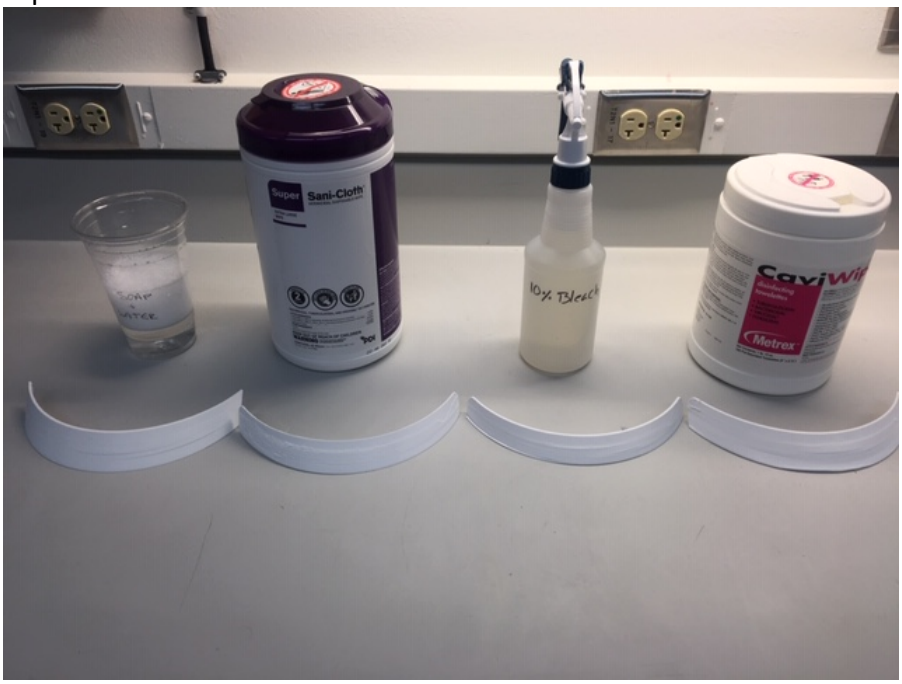

Figure 12: Printed parts prior to disinfection

PLA 3D-printed parts after disinfected 10x:

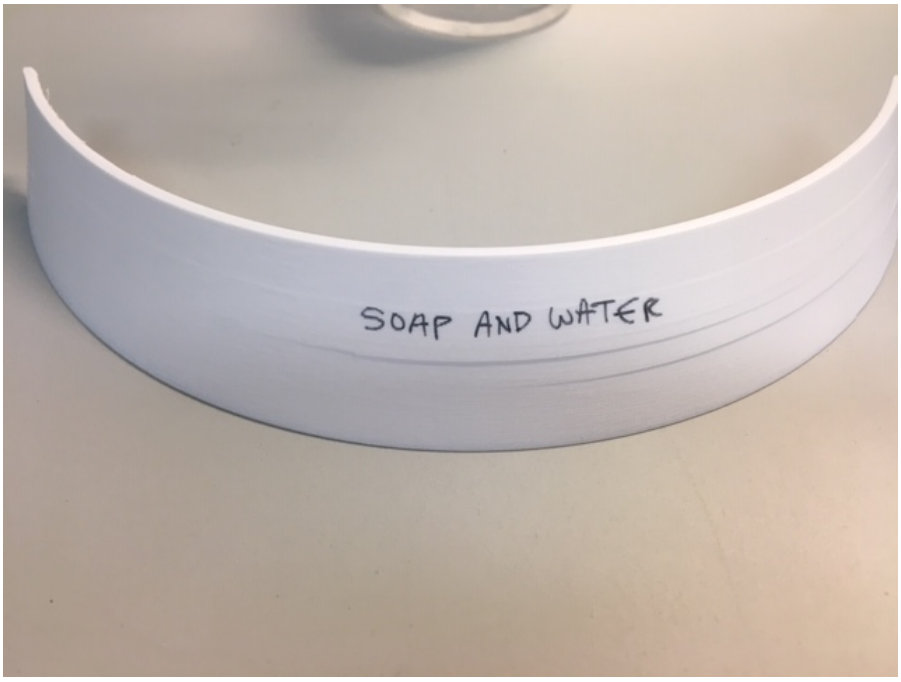

Figure 13: PLA disinfected 10x with a soap and water solution

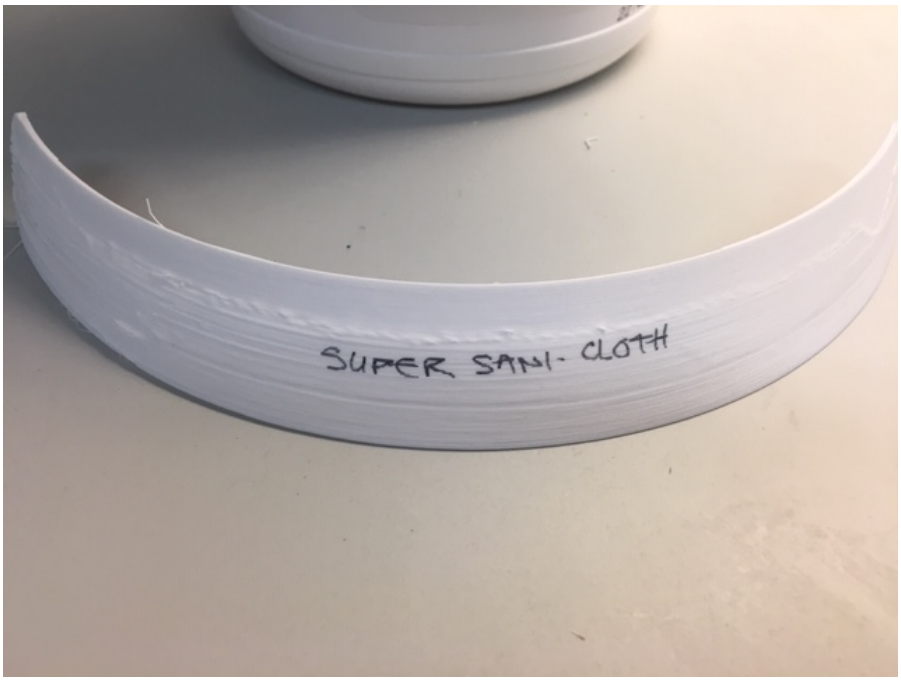

Figure 14: PLA disinfected 10x with a Super Sani-Cloth

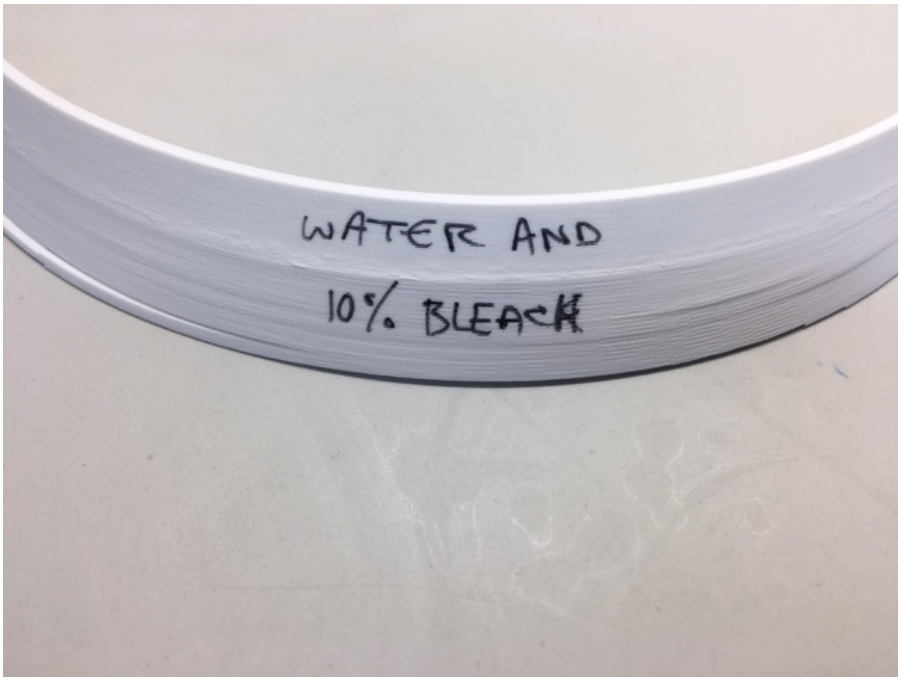

Figure 15: PLA disinfected 10x with a 10% bleach solution

Figure 16: PLA disinfected 10x with a soap and water solution

Handler Tracking Sheet

3D Print Collection

Name	Initial	Date
_____	_____	_____

Assembly

_____	_____	_____

Delivery

_____	_____	_____